

AMENDMENTS TO THE DRAWINGS

Please replace the amended Figure 4, filed March 6, 2006, with the replacement amended Figure 4 enclosed herewith.

REMARKS

Status of the claims

Claims 1-2, 4-6, 8, 13-19, 21-26, 28-29, 31-32, 34-37, 43-44, 50-51, and 61-62 are pending and rejected herein. Claims 3, 7, 9-13, 20, 27, 29-33, 38-42, 45-49, and 52-69 are canceled previously or herein. Claims 1, 8, 34, 43, and 50 are amended. No new matter is added.

Objection/Amendments to the claims

The claims are objected to for not invoking 35 U.S.C. §112, 6th paragraph, in not using means plus function language. Applicants have cancelled claim 13. Claims 1, 8, 34, 43, and 50 are amended to recite "means for" where appropriate. Accordingly, in view of the amendments presented herein, Applicants respectfully request that the objection to the claims be withdrawn.

Claim 1 also is amended to incorporate the limitations of dependent claims 29 and 31. Amended claim 1 now recites the claim elements of a container operably connected distally to the device having an opening therethrough adapted to deliver an abrasive material therein to the tissue or to collect an ablated tissue or other biomolecule therein from an ablation site on the tissue (pg. 25, ll. 5-13), a reservoir adapted to contain a pharmaceutical operably connected to the device and a permeable membrane adapted to controllably release the pharmaceutical. Also, claim 1 is amended to recite an actuator having an inferior surface adapted to contact an abrasive material deliverable onto a tissue (pg. 41, ll. 8-11) and means for driving the actuator at a high frequency.

For claims 34, 43 and 50, the preambles are amended to clarify claim language and to recite a means for controlling feedback monitoring of a change in an electrical property (claim 34), an optical property (claim 43) and a thermal property (claim 50) of the tissue tissue. No new matter is added in any claim amendment.

Objection/Amendment to the specification

The Examiner objects that the amendment to the specification adding separate containers 75,76 for a pharmaceutical and the ablated tissue is new matter. The Examiner

also objects that the addition of the absorptive material in contact with the treated skin or in the container 75 is new matter.

The specification is amended, as described supra, to describe a device comprising a container 70 with an opening 75 therethrough operably connected distally to the device which may contain the abrasive material such that the abrasive is delivered to the surface to be ablated, may collect ablated tissue or may collect a biomolecule from the site of ablation (pg. 25, ll. 5-13). Thus, Applicants submit that no new matter is contained in this amendment. Accordingly, Applicants request that the objection to the specification be withdrawn.

Objection/Amendment to the drawings

The Examiner objects that, in Figure 4, the addition of a container 75 and an absorptive medium 70 together in the container is not supported in the specification. The Examiner also objects to the addition of a separate container 76 to hold the abrasive as being unsupported by the specification. The Examiner also states that the drawings disclose containers 75,76 with a height higher than that of element 12 or element 42 or having a height below element 55 and that the specification does not disclose the location of the two containers.

Applicants have amended Fig. 4 to delete container 76, delete the absorptive material 70 and to depict a container 70 with an opening 75 therethrough description of Fig. 4, as discussed supra. With regard to the location of the container, the specification discloses that a container may be operably connected distally to the device (pg. 25, ll. 5-7). As electrode 45 is disclosed as being in a distal position, then so is amended container 70. The container also is positioned to be deliver the abrasive or to collect ablated tissue or a biomolecule from ablated membrane 18. Respectfully, Applicants submit that the height shown for amended container 70 is an appropriate representation of the container as are the other elements of the device.

Applicants submit that amended Fig. 4 contains no new matter. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

The 35 U.S.C. § 112, first paragraph, rejections

Claims 1-2, 4-6, 8, 13-19, 21-26, 28-29, 31-32, 34-37, 43-44, 50-51, and 61-62 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written

description requirement or the enablement requirement. Applicants respectfully traverse this rejection.

The Examiner states that in amended claim 1 there is no support for the phrase "means to collect a tissue or biochemical sample during ablation". Applicants have deleted this phrase. The Examiner states that in amended claim 1 there is no support for the phrase "wherein said pharmaceutical is in a separate container". Applicants have deleted this phrase. The Examiner states that in claim 8, the recitation of "pressurized gas" is not enabled by the specification. Applicants have deleted the term.

Applicants have canceled claims 13, 29 and 61-62. Accordingly, in view of the claim amendments presented herein, Applicants respectfully request that the rejection of claims 1-2, 4-6, 8, 14-19, 21-26, 28, 31-32, 34-37, 43-44, and 50-51, under 35 U.S.C. § 112, first paragraph, be withdrawn.

The 35 U.S.C. § 112, second paragraph, rejections

Claims 1-2, 4-6, 8, 13-19, 21-26, 28-29, 31-32, 34-37, 43-44, 50-51, and 61-62 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

The Examiner states that in claim 1, the term "separate" is indefinite as it can be interpreted as separation by physical distance or distinct. Applicants have deleted the term. Applicants have canceled claims 13, 29 and 61-62. Accordingly, in view of the claim amendments presented herein, Applicants respectfully request that the rejection of claims 1-2, 4-6, 8, 14-19, 21-26, 28, 31-32, 34-37, 43-44, and 50-51 under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. § 103(a)

Claims 1, 2, 4-6, 8, 14, 18-19, 21-26 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Suroff** (US Patent No. 5,150,492) in view of **Earl** (U.S. Pub. No. 2004/0020508). Applicants respectfully traverse this rejection.

The Examiner states that **Suroff** discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency and a means to collect tissue. The device is capable of use with

various tissues and various lubricants, i.e. water, and pharmaceuticals. The Examiner also states that **Suroff** does not explicitly disclose a separate container, but that **Earl** discloses a separate container 19 for containing a desired substance such as a pharmaceutical for delivery (Figs. 5-7). The Examiner concludes that that it would be obvious to one of ordinary skill in the art to modify the device of **Suroff** with the container as taught by **Earl** to provide a convenient container for quick access to the desired substance and efficiency.

Suroff teaches an ultrasonic toothbrush with an exchangeable ultrasonic implement, which can be connected to an ultrasonic power means. The ultrasonic toothbrush is designed to remove tartar, stain as well as interproximal deposits for efficient cleaning of teeth (col. 7, II. 19-24). This ultrasonic toothbrush is specifically designed such that adults and children (col. 2, II. 66-67) can safely use it at home without special knowledge or training.

Earl teaches a folding toothbrush having a piston chamber for toothpaste in the handle for dispensing the toothpaste through passages leading to the bristles. A screw cap at the end of the handle rotates to move the piston down the chamber to push the toothpaste out. (PP [0010]-[0014].

Applicants invention in considering amended independent claim 1 is as described supra. Applicants have incorporated the limitations of claims 29 and 31 into amended independent claim 1 such that the device comprises a reservoir adapted to contain a pharmaceutical operably connected to the device and a permeable membrane adapted to controllably release the pharmaceutical and a container operably connected distally to the device having an opening therethrough adapted to deliver an abrasive substance therein to the tissue or to receive a tissue or other biomolecule therein from an ablation site on the tissue. Claims 29 and 31 are not identified as being obvious over **Suroff** in view of **Earl**, therefore the combination of **Suroff** with **Earl** cannot render amended independent claim 1 obvious.

In addition, the combination of **Suroff** with **Earl** neither teach nor suggest that the actuator has an abrasive inferior surface that contacts an abrasive deliverable to the tissue as in amended independent claim 1. Furthermore, one must consider the prior art as a whole. **Suroff** and **Earl** teach an ultrasonically powered toothbrush and a manual toothbrush, respectively. Neither toothbrush can ablate tissue, but are specifically designed to remove substances which are not tissue, i.e., food particles, plaque and calculus, from the teeth and gum tissue. It is well known in the art that toothbrushes are designed and intended to be used in a

manner not to damage teeth and gums. It is well established that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. Simply modifying the toothbrush of **Suroff** by incorporating a container into the toothbrush as taught in **Earl** does not result in Applicants' invention as recited in amended independent claim 1.

Thus, at a minimum, as the combination of **Suroff** with **Earl** does not teach the claim elements of incorporated dependent claims 29 and 31, amended independent claim 1 cannot be obvious over the combination. Applicants have canceled claim 62. Furthermore, as claims 2, 4-6, 8, 14, 18-19, 21-26 and 62 depend directly or indirectly from amended independent claim 1, they also are not obvious over the combination of **Suroff** with **Earl**. Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 14, 18-19, and 21-26 under 35 U.S.C. § 103(a) be withdrawn.

Claims 1, 2, 4-6, 8, 13-18, 20-26 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Bernaz** (WO 02/053046, US pub. No. 2004/0092956, English version) in view of **Tapper** (U.S. Patent No. 6,235,013). Applicants traverse this rejection. Applicants respectfully point out that claim 20 was canceled in a previous response.

The examiner states that **Bernaz** discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water and electrophoretic driving means, and a container formed by ridges capable of holding pharmaceuticals until delivery by mechanical pressure (PPs 0019, 0025, 0031-0032, 0046-0047, 0052, 0055, and 0062-0063). The Examiner also states that **Bernaz**'s device is capable of use with various tissues and pharmaceuticals. The Examiner states further that **Bernaz** does not explicitly disclose the use of a separate container for the pharmaceutical, but that **Tapper** teaches the use of a separate pharmaceutical container (18a & 18b in Figs. 2-3). The Examiner concludes it would have been obvious for one of ordinary skill in the art to modify the device of **Bernaz** with the teachings of **Tapper** to provide a convenient container for quick access to the desired substance and efficiency.

Bernaz teaches a device for cosmetic skin dermabrasion that has a curved smooth U-shaped abrasive surface, held by a support mounted in a housing, which is driven to oscillate about its axis to effect the abrasion of the epidermis (Abstract; PP 0016). Alternatively, the device comprises a support piece with a double reversible face, including the curved abrasive surface and on the other side a surface equipped with striations designed for a massage treatment (PP [0020], [0059]; Fig. 5b).

Tapper teaches an iontophoretic treatment system where the electrical current between a pair of electrodes is periodically reversed at low frequencies during an iontophoretic procedure to deliver treatment substances (Abstract). The device comprises two semicircular electrode chambers including a gel containing a drug or felt pads containing the drug therein (col. 8, ll. 8-18).

Applicants invention in considering amended independent claim 1 is as described supra. Applicants have incorporated the limitations of claims 29 and 31 into amended independent claim 1 as discussed supra. Claims 29 and 31 are not identified as being obvious over **Bernaz** in view of **Tapper**, therefore the combination of **Bernaz** with **Tapper** cannot render amended independent claim 1 obvious. The combination of **Bernaz** with **Tapper** require the use of an electromagnetic flux or electric current to drive a drug across the skin and not the simple permeation as recited in amended independent claim 1.

In addition, the combination of **Bernaz** with **Tapper** neither teach nor suggest that the actuator has an abrasive inferior surface that contacts an abrasive deliverable to the tissue as in amended independent claim 1. **Bernaz** specifically states that prior devices using abrasives such as aluminum hydroxide microcrystals or projected corundum microcrystals are not for skin dermabrasion and in particular not for microepidermabrasion (PP [0002]-[0003], [0014]). Thus, the combination specifically teaches away from using an abrasive.

Thus, at a minimum, as the combination of **Bernaz** with **Tapper** does not teach the claim elements of incorporated dependent claims 29 and 31, amended independent claim 1 cannot be obvious over the combination. Applicants have canceled claims 13 and 62. Furthermore, as claims 2, 4-6, 8, 14-18, and 21-26 depend directly or indirectly from amended independent claim 1, they also are not obvious over the combination of **Bernaz** with **Tapper**. Accordingly, in view of the claim amendments and arguments presented herein, Applicants

respectfully request that the rejection of claims 1, 2, 4-6, 8, 14-18, and 21-26 under 35 U.S.C. § 103(a) be withdrawn.

Claims 1, 2, 4-6, 8, 13-26, 28, 31, 34-37, 43-44 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Weaver** et al. (US Pub. No. 2002/006553) in view of **Tapper**. Applicants respectfully traverse this rejection. As stated *supra*, claim 20 was cancelled in a previous response.

In considering claim 1, the Examiner states that **Weaver** et al. discloses a device for ablating tissue using an abrasive member (microparticle) that can be driven at high frequencies to contact abrasive material (microparticles) delivered onto a tissue via a container (0042-0045). The Examiner also states that the pressurized gas driving forces disclosed by **Weaver** et al. are capable of driving microparticles at high frequencies by using intermittent driving forces. In addition the Examiner states that **Weaver** discloses means to deliver a pharmaceutical to the tissue (PP [0113]-[0117] that inherently includes a container and that can be applied using electrophoresis. The Examiner states further that **Weaver** does not explicitly disclose the use of a separate container for the pharmaceutical, but that **Tapper** teaches the use of a separate pharmaceutical container (18a & 18b in Figs. 2-3). The Examiner concludes it would have been obvious for one of ordinary skill in the art to modify the device of **Bernaz** with the teachings of **Tapper** to provide a convenient container for quick access to the desired substance and efficiency.

Weaver et al. disclose an apparatus used for creating microconduits by impingement of accelerated microparticles thereon to scission the tissue for localized molecular and ionic transport to/from tissue (Abstract). The device comprises a means for accelerating a plurality of microparticles to a velocity that causes penetration into a tissue surface upon impingement thereon, a means for directing the microparticles towards a region of tissue surface and a means to allow the microparticles to impinge and to penetrate a region of the tissue surface ([0065]). The accelerating means is a pressurized gas, a pressurized flowing liquid, a vacuum, or a rapidly moving solid surface such as an impeller ([0041]-[0048]). The means to direct the microparticles is a mask such as a membrane comprising one or more microholes through which the microparticles may penetrate the tissue surface ([0068; Fig. 1]) or is a beam collimator to direct a scannable collimated beam of

microparticles toward the tissue surface ([0076]; [0086]; Fig. 2). The means to allow the microparticles to impinge and penetrate the tissue may be a gating switch or other ON/OFF means or a timing or metering device ([0079]-[0081]).

Applicants have canceled claims 13 and 62 and incorporated the limitations of dependent claim 29 into amended independent claim 1, as discussed supra. Claim 29 is not identified as being obvious over **Weaver** et al. in view of **Tapper**, therefore the combination of **Weaver** et al. with **Tapper** cannot render amended independent claim 1 obvious. The combination of **Weaver** et al. with **Tapper** require the use of an electrical current in an electrophoretic or iontophoretic process to drive a drug across the skin and not the simple permeation as recited in amended independent claim 1.

In addition, the combination of **Weaver** et al. with **Tapper** neither teach nor suggest that the actuator has an inferior surface that contacts an abrasive deliverable onto the tissue as in amended independent claim 1. Respectfully, Applicants strongly disagree with the Examiner's statement that the abrasive microparticles propelled from a distance to scission the skin in **Weaver** et al. constitute an abrasive member or surface. By definition a member is a constituent piece of a complex structure, device or apparatus and not a substance upon which the structure containing the member operates or utilizes.

In addition the combination of **Weaver** et al. with **Tapper** teach that microparticles are propelled from a distance into the skin to cut microchannels or microconduits therein. No suggestion or teaching is found in the combination to deliver abrasive particles onto the tissue surface to be subsequently contacted by an inferior surface of the actuator. The device in **Weaver** et al. is specifically designed to form the microconduits into the skin and not to ablate tissue across the tissue surface. No component part of the device in **Weaver** et al. contact abrasive particles on the tissue surface. In this aspect **Weaver** et al. teaches away from the instant amended claim 1.

Thus, at a minimum, as the combination of **Weaver** et al. with **Tapper** does not teach the claim elements of incorporated dependent claim 29, amended independent claim 1 cannot be obvious over the combination. Applicants have canceled claims 13 and 62. Furthermore, as claims 2, 4-6, 8, 14-19, 21-26, 28, 31, 34-37, and 43-44 depend directly or indirectly from amended independent claim 1, they also are not obvious over the combination of **Weaver** et al. with **Tapper**. Accordingly, in view of the claim amendments and arguments

presented, Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 14-19, 21-26, 28, 31, 34-37, and 43-44 under 35 U.S.C. §103(a) be withdrawn.

Claims 1, 2, 4-6, 8, 13-14, 17, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hickok** et al. (US Pub. No. 2003/0096213) in view of **Tapper**. Applicants respectfully traverse this rejection.

The Examiner states that **Hickok** discloses a device for ablating tissue using a diamond abrasive on the ablating device and a supply of pharmaceuticals to be delivered to the ablation site. The Examiner states further that **Weaver** does not explicitly disclose the use of a separate container for the pharmaceutical, but that **Tapper** teaches the use of a separate pharmaceutical container (18a & 18b in Figs. 2-3). The Examiner concludes it would have been obvious for one of ordinary skill in the art to modify the device of **Bernaz** with the teachings of **Tapper** to provide a convenient container for quick access to the desired substance and efficiency.

Hickok et al. teaches an ultrasonic dental tool with a rounded tip that is formed for cleaning, finishing and polishing tooth areas. An ultrasonic transducer vibrates the tip at the end of a shaft. The tip may have a coating of diamond particles adhered thereto or may have a roughened surface (PP [0041]-[0043]). The shaft has a port for delivery of fluid through the tip to the work area (Abstract; PP [0009]-[0010]).

Applicants have incorporated the limitations of claims 29 and 31 into amended independent claim 1 as discussed supra. Claims 29 and 31 are not identified as being obvious over **Hickock** et al. in view of **Tapper**, therefore the combination of **Hickock** et al. with **Tapper** cannot render amended independent claim 1 obvious. Also, the combination of **Hickock** et al. with **Tapper** neither teach nor suggest an actuator with an inferior surface adapted to contact an abrasive which is deliverable onto the tissue surface. The diamond coated or surface roughened tip in **Hickock** et al. is specifically required and is necessary to enable precision work on, in or around pockets formed between the tooth and gingiva.

Thus, at a minimum, as the combination of **Hickok** et al. with **Tapper** does not teach the claim elements of incorporated dependent claims 29 and 31, amended independent claim 1 cannot be obvious over the combination. Applicants have canceled claim 13. Furthermore, as claims 2, 4-6, 8, 14-18, and 21-26 depend directly or indirectly

from amended independent claim 1, they also are not obvious over the combination of **Hickock et al.** with **Tapper**. Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 1, 2, 4-6, 8, 14, 17, and 21-25 under 35 U.S.C. § 103(a) be withdrawn.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bernaz** in view of **Tapper** as applied to claims 26 and 1 above, and further in view of **Eggers** (US Patent No. 6,066,134). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz** in view of **Tapper** discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device. The Examiner also states that **Eggers** teaches monitoring feedback using a heartbeat to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art to use the teachings of **Eggers** in the device of **Bernaz** to increase the safety of the ablation procedure for better patient outcome.

Eggers et al. teach an electrosurgical probe comprising a shaft having an electrode array, as active electrode, at its distal end, a return electrode recessed within the shaft and a connector at its proximal end for coupling the electrode array to a high frequency power supply (Abstract). **Eggers et al.** teach monitoring the temperature of the surface of the electrode array to regulate current flow if the temperature exceeds selected limits (col. 14, ll. 44-63). **Eggers et al.** teach monitoring the heartbeat so that the high frequency voltage is pulsed to cut or ablate heart tissue to form a revascularization channel during systole of the heart and a thermal property of the tissue to perform safe ablation of heart tissue during a revascularization procedure (col. 23, ll. 43-56).

As discussed *supra*, **Bernaz** in combination with **Tapper** cannot render amended independent claim 1 obvious for not teaching, at a minimum, the claim elements of dependent claims 29 and 31. Combining **Eggers et al.** with **Bernaz** and **Tapper** does not remedy these deficiencies.

Claims 34-37 depend directly or indirectly from amended claim 1. These claims limit the method of amended claim 1 to further comprising a means for controlling feedback monitoring of a change in an electrical property of said tissue during ablation such as monitoring change in an endogenous electrical signal, e.g., heartbeat, during ablation using

active/return electrodes. **Eggers** et al. specifically teach using high frequency voltage delivered from an active electrode in an electrosurgical probe to ablate heart tissue to form a revascularization channel. **Eggers** et al. specifically teach using an electrode array to monitor a thermal property to control ablation. Particularly, **Eggers** et al. teach monitoring the heartbeat so that the channel is ablated only during systole of the heart. This is not monitoring a change in the electrical activity of the heart during ablation, but rather monitoring a heartbeat to know when to ablate.

Thus, as the combination of **Bernaz** and **Tapper** with **Eggers** et al. cannot render amended independent claim 1 obvious, then neither are dependent claims 34-35 rendered obvious by the combination. Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 34-37 under 35 U.S.C. § 103(a) be withdrawn.

Claims 50 and 51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Weaver** in view of **Tapper** as applied to claim 1 above and further in view of **Eggers**. Applicants respectfully traverse this rejection.

The Examiner states that **Weaver** in view of **Tapper** discloses the claimed invention including monitoring temperature, but is silent on the structure relied upon to monitor temperature (0117). The Examiner states that **Eggers** teaches monitoring a thermal property of the tissue using infrared sensors and that the use of an infrared detector and controller to analyze data from an energy source and detector is inherent in the disclosed device because it measures temperature. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to use the teachings of **Eggers** in the device of **Weaver** in order to maintain safe operating temperatures during the ablation procedure. Applicants respectfully disagree.

As discussed supra **Weaver** et al. in combination with **Tapper** cannot render amended independent claim 1 obvious for not teaching, at a minimum, the claim elements of dependent claim 29. Combining **Eggers** et al. with **Weaver** et al. and **Tapper** does not remedy this deficiency.

Claims 50-51 depend directly or indirectly from amended claim 1. These claims limit the method of amended claim 1 to further comprising a means for controlling

feedback monitoring of a change in a thermal property of tissue, such as thermal diffusivity or thermal conductivity, using infrared detectors. **Eggers** et al. specifically teach using an electrode array to monitor a thermal property to control ablation.

Thus, as the combination of **Weaver** et al. and **Tapper** with **Eggers** et al. cannot render amended independent claim 1 obvious, then neither are dependent claims 50-51 rendered obvious by the combination. Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claims 50-51 under 35 U.S.C. § 103(a) be withdrawn.

Claim 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over **Bernaz**, **Weaver** et al. or **Hickok** et al. in view of **Tapper**, as applied to claim 20 above, and further in view of **Unger** (US patent No. 6,416,740). Applicants respectfully traverse this rejection. Respectfully, claim 20 was canceled in a previous response. Applicants assume the rejection is as applied to claim 1 above.

The Examiner states that **Bernaz**, **Weaver** et al. or **Hickok** et al. in view of **Tapper** discloses the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. The Examiner states that **Unger** teaches the use of a permeable membrane to release a pharmaceutical in a patch applied to the skin of a patient. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of **Unger** in the device of **Bernaz**, **Weaver** et al. or **Hickok** et al. in order to provide a convenient drug delivery system through the skin to achieve therapeutic results.

Unger teaches an acoustically active targeted therapeutic delivery system where ultrasound enhances delivery of the therapeutic (Abstract). The therapeutic, e.g. steroid prodrugs, together with a penetration enhancer may be administered transdermally in a patch or reservoir with a permeable membrane in a patch applied to the skin of a patient (col. 69, II. 11-14).

Bernaz, **Weaver** et al., **Hickok** et al. and **Tapper** are as described *supra*. Applicant's invention as recited in amended independent claim 1 is as discussed *supra* where the claim limitations of dependent claim 29 are incorporated therein and claim 29 is canceled. As discussed *supra*, **Bernaz** or **Hickok** et al. in combination with **Tapper** cannot render

amended independent claim 1 obvious for not teaching, at a minimum, the claim elements of dependent claim 31. Combining **Unger** with **Bernaz** or **Hickock** et al. and **Tapper** does not remedy this deficiency. Also, as discussed *supra*, **Weaver** et al. in combination with **Tapper** cannot remedy amended independent claim 1 obvious, for failing, at a minimum, to teach or suggest that the actuator has an inferior surface that contacts an abrasive material deliverable onto the tissue surface. Combining **Unger** with **Bernaz**, **Weaver** et al., or **Hickok** et al. and **Tapper** does not remedy these deficiencies.

Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claim 29, as incorporated into amended claim 1, under 35 U.S.C. § 103(a) be withdrawn.

Claims 19, 61 and 62 are rejected under 35 U.S.C. § 103(a) as being unpatentable over **Bernaz**, **Weaver** et al. or **Hickok** et al. in view of **Tapper**, as applied to claim 1 above, and further in view of **Melbouci** et al. (US Patent No. 6, 562, 090). Applicants respectfully traverse this rejection.

The Examiner states that **Bernaz**, **Weaver** et al. or **Hickok** et al. discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. The Examiner also states that **Melbouci** et al. teach using water and glycerol with a lubricant to provide a stabilized suspension of abrasive in lubricant (claim 1). The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to use teachings of **Melbouci** et al. in the device of **Weaver** et al. in order to facilitate the use of the abrasive.

Melbouci et al. disclose a fluid abrasive for dentifrice systems, i.e., toothpastes, that may comprise the abrasive, a water-swellable or water-soluble polymer and water mixed with glycerol (col. 3, ll. 10-44). **Bernaz**, **Weaver** et al. or **Hickok** et al. in combination with **Tapper** cannot render amended independent claim 1 obvious for not teaching, at a minimum, the claim elements of dependent claim 29 nor, in the case of **Bernaz** or **Hickok** et al. in combination with **Tapper**, the claim elements of dependent claim 31. Combining **Melbouci** et al. with **Bernaz**, **Weaver** et al. or **Hickok** et al. and **Tapper** does not remedy this deficiency.

Furthermore, claim 19 depends directly from dependent claim 18 which depends directly from amended independent claim 18 and further limits the lubricant recited

in dependent claim 18. In fact, dependent claim 18 is not identified by the Examiner as being obvious over **Hickok** et al. in view of **Tapper**. Therefore, in view of this alone, claim 19 cannot be obvious over the combination of **Hickok** et al. and **Tapper** nor **Hickok** et al. and **Tapper** with **Melbouci** et al.

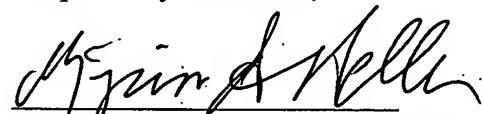
Thus, as the combination of **Bernaz**, **Weaver** et al. or **Hickok** et al. and **Tapper** with **Melbouci** et al. cannot render amended independent claim 1 obvious, then neither is dependent claim 19 rendered obvious by the combination. Accordingly, in view of the claim amendments and arguments presented herein, Applicants respectfully request that the rejection of claim 19 under 35 U.S.C. §103(a) be withdrawn.

Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over **Weaver** as applied to claim 31 above, and further in view of **Fuisz** (US Patent No. 3,918,433). Applicants respectfully traverse the rejection.

Applicants have canceled claim 32 thereby obviating the rejection. Thus, Applicants request that the rejection of claim 32 under 35 U.S.C. § 103(a) be withdrawn.

This is intended to be a complete response to the Final Office Action, mailed June 1, 2006. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record. Applicants file this Response after Final with a Request for Continued Examination including a Petition for a Three Month Extension of Time. Please charge the \$395 RCE fee and the \$510 petition fee to the credit card identified on the enclosed Form PTO-2038. **Only in the absence** of Form PTO-2038, please debit any applicable fees from Deposit Account No. 07-1185 upon which the undersigned is allowed to draw.

Respectfully submitted,



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